REMARKS

This responds to the Office Action dated July 27, 2007. Claims 1, 13, and 19 are amended, claims 18 and 20 are canceled, and claims 21-23 are added; as a result, claims 1-17, 19, and 21-23 are now pending in this application. No new matter has been added by way of any amendment or new claim.

Claim Objections

Claim 13 was objected to because of the following informality: Claim 13 recited "*a combined amount of up between about...*". As suggested by the Examiner, claim 13 has been amended to recite "of between about". Applicant thanks the Examiner for this helpful suggestion. The amendment to claims 13 is believed to obviate the objection. Reconsideration and withdrawal of the objection is respectfully requested.

§103 Rejection of the Claims

Claims 1-17 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tapolsky et al. (U.S. Pat. No. 5,800,832) in view of Bowman et al. (U.S. Pat. No. 6,372,245) or Wong et al. (U.S. Pat. No. 6,331,313). This rejection is respectfully traversed.

A Prima Facie Case of Obviousness Cannot Be Maintained:

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). If the Examiner does not establish a *prima facie* case, the applicant is under no obligation to submit evidence of non-obviousness. M.P.E.P. § 2142. To establish a *prima facie* case of obviousness, three criteria must be met.

First, the reference (or references) relied upon must teach or suggest all the limitations of the claims. See *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art.").

Second, the reference (or references) relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that

would have motivated the skilled artisan to modify a reference or to combine references. See *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988); *In re Skinner*, 2 U.S.P.Q.2d 1788, 1790 (Bd. Pat. App. & Int. 1986).

Third, the proposed modification of the reference (or references) relied upon must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. In other words, a hindsight analysis is not allowed. See *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991); *In re Erlich*, 3 U.S.P.Q.2d 1011, 1016 (Bd. Pat. App. & Int. 1986).

Because the criteria required to establish and maintain a *prima facie* case of obviousness cannot be met, as discussed below, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103 is respectfully requested.

***There is no suggestion or incentive to* modify *or* combine *the cited patents*:**

The Examiner has not met the burden of showing sufficient motivation for one of ordinary skill in the art at the time of the invention to modify the reference teachings in a manner necessary to arrive at the presently claimed invention. Even in combination, the disclosures of Tapolsky, Bowman, and Wong would have to be modified in order to arrive at Applicant's claimed invention. The Examiner should set forth in the Office Action "an explanation why one of ordinary skill in the art at the time of the invention was made would have been motivated to make the proposed modification" (emphasis added). M.P.E.P. § 706.02(j).

The Bowman '245 patent describes once-a-day eye drops that include the bioerodible polymer poly(2,2-dioxy-*trans*-1,4-cyclohexane dimethylene tetrahydrofuran) (see, for example, the Abstract and the Examples). The Wong '313 patent describes a cylindrical Teflon® tube that is surgically implanted into the eye, wherein a drug is released through an orifice in the tube (see the Abstract and column 2, lines 37-41). Bowman and Wong do not contain any suggestions, or provide any incentive, that would motivate the skilled artisan to modify the bioerodible pharmaceutical delivery system described by Tapolsky in a manner necessary to arrive at the method for locally delivering a pharmaceutical via an ocular surface by contacting the ocular surface with a mucoadhesive film claimed by Applicant. The Examiner bears the burden of showing sufficient suggestion or incentive that would have motivated the skilled artisan to

modify the Tapolsky '832 patent in view of the Bowman '245 patent or the Wong '313 patent. Applicant respectfully submits that the Examiner has not met this burden. Absent any showing of suggestion, motivation, or incentive to modify Tapolsky, the rejection under 35 U.S.C. §103(a) is improper.

Additionally, Bowman and Wong do not contain any suggestions, or provide any incentive, that would motivate the skilled artisan to combine the bioerodible pharmaceutical delivery system described Tapolsky in a manner necessary to arrive at the method for locally delivering a pharmaceutical via an ocular surface by contacting the ocular surface with a mucoadhesive film claimed by Applicant. The Examiner bears the burden of showing sufficient suggestion or incentive that would have motivated the skilled artisan to combine the Tapolsky '832 patent in view of the Bowman '245 patent or the Wong '313 patent. Applicant respectfully submits that the Examiner has not met this burden. At page 7 of the Office Action, the Examiner states that the expected result of combining Tapolsky and Bowman "would be an enhanced method of drug delivery for effectively combating infections of the eye." The Examiner, however, has not presented any articulable facts that would lead one to the conclusory statement set forth in the Office Action. Absent any showing of suggestion, motivation, or incentive to combine Tapolsky, the rejection is improper.

Bowman Teaches Away From Combinations with Tapolsky:

The disclosure of Bowman **teaches away** from any combination of the Tapolsky '832 patent with the Bowman '245 patent or the Wong '313 patent. The Bowman '245 patent, at column 1, lines 33-36, states that "[g]elatin lamellae or other films or sheets, ocular inserts and non-aqueous suspensions and emulsions all can cause immediate pain and continuing discomfort and can also interfere with vision." (Emphasis added.) Accordingly, Bowman teaches that using the Tapolsky system, even with a glaucoma agent of Bowman or Wong, would likely result in immediate pain, continuing discomfort, and interference with vision. Thus the Bowman '245 patent teaches away from the use of both the Tapolsky film for mucosal surfaces and the Wong ocular insert for the eye. Therefore, one skilled in the art would not be motivated to modify or combine Bowman and Tapolsky, or Wong and Tapolsky, because Bowman teaches that doing so would lead to pain, discomfort, and hindered vision in the patient being treated. On the contrary,

one skilled in the art would be motivated to use elements other than a mucoadhesive film or an ocular insert when attempting to provide an enhanced method of drug delivery to the eye because pain, discomfort, and hindered vision would sought to be avoided. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103.

***The references lack all the limitations of the claims and en expectation of success*:**

At page 6 of the Office Action, line 14, the Examiner acknowledged that the Tapolsky '832 patent does not teach or suggest antiglaucoma agents. In addition, the Tapolsky '832 patent does not teach or suggest a method for locally delivering a pharmaceutical via an ocular surface by contacting the ocular surface with a mucoadhesive film. Neither the Bowman '245 patent nor the Wong '313 patent remedies this deficiency. Additionally, even if all the claim limitations could be found in the combination of Tapolsky, Bowman, and Wong, the Examiner has not presented any facts or reasoning that would show why there would be any expectation of success. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103.

RESERVATION OF RIGHTS

In the interest of clarity and brevity, Applicant may not have addressed every assertion made in the Office Action. Applicant's silence regarding any such assertion does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. Applicant reserves all rights to pursue any cancelled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 359-3270 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date 12/27/2007

By / /
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this ____ day of December 2007.

KIMBERLY BROWN

Name

Signature